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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,487	04/12/2006	Michael Jemec	5002-1088	3422

466 7590 04/02/2008

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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,487	JEMEC, MICHAEL	
	Examiner	Art Unit	
	ABDEL A. MOHAMED	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/12/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF PRIORITY, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. This application filed under 35 U.S.C. 371 on 04/12/06 having a filing date of 09/16/04 of PCT/IB04/03045. Acknowledgement is made of Applicant's claim priority based on Switzerland Application Numbers 01740/03 having filing date of 10/13/03. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. In view of Applicant's request claims 1-3 have been canceled and claims 4-6 have been added. Claims 4-6 are now pending in the application.

The references cited in the Search Report from the EPO have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO/SB/08A and 08B form, must be filed within the set period for reply to this Office action. As a courtesy, WO 01/64236 A2, has been provided by examiner and cited on the PTO-892, but a copy of Stoléru et al. (1993) was not readily available.

OBJECTION TO THE SPECIFICATION

2. The specification is objected because there are no Headings disclosed in the disclosure and the following guidelines illustrate the preferred layout and content for patent application. These guidelines are suggested for the Applicant's use:

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) Or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3. Also, the specification is objected because the priority data of this application should be updated in the specification. Appropriate correction is required. Further, the disclosure is objected on page 2, lines 7-9 in the recitation "The subject of the present invention is therefore the use of LH described in the attached Claim 1". There is no claim 1 because claim 1 has been canceled in the preliminary amendment filed 04/12/06. Thus, appropriate correction is required.

CLAIMS REJECTION-35 U.S.C. 112, 1st PARAGRAPH

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the instant specification for the claimed method for **treating a lack of or low libido and/or a difficulty in reaching orgasm in female subjects**, comprising administering parenterally or orally by means of tablets to said woman an effective amount of Luteinizing Hormone (LH) as claimed in claims 4-6. The specification alleges that the inventors being doctors and researchers and based on their observation that female body secretes LH before the ovulation, they believed that the administration to female subjects of synthetic LH could remedy a lack of or low libido and the difficulty in reaching orgasm. However, there is no pharmaceutical formulation administered to female subjects an effective amount of LH parenterally or orally by means of tablets to **treat a lack of or low libido and/or a difficulty in reaching orgasm**. There is no *in vivo* showing or data or a single example to demonstrate the administration of an effective amount of LH (which is not known) for the effectiveness of the method for **treating a lack of or low libido and/or a difficulty in reaching orgasm in female subjects** in the manner claimed in claims 4-6.

5. Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are no teachings in the specification to show the enablement of a method for **treating female subjects**, comprising administering parenterally or orally by means of tablets to

said woman an effective amount of Luteinizing Hormone (LH) for a method of treating a lack of or low libido and/or a difficulty in reaching orgasm in female subjects.

The specification discloses the term "female subjects" in conjunction with treatment while the term "woman" is mentioned with menstrual cycle. Further, the term "female subjects" encompasses all kinds of female including animals, insects, birds, mammals, human which includes woman, etc. Thus, there is no specific data or evidence or **even one example** to show a method for **treating a female subject**, comprising administering parenterally or orally by means of tablets to said woman an effective amount of LH for a method of treating a lack of or low libido and/or a difficulty in reaching orgasm in female subject. Thus, the scope of **treating female subject** in the manner claimed in claims 4-6 are not enabled and speculative.

Therefore, the administration of the formulation claimed to **treat all kinds of female subjects**, which may include human female (i.e. woman) or non-human female, would include those preparation/formulation that have not been shown or taught to be useful or enabled by the disclosed method of making and using the invention. Moreover, undue experimentation is necessary to determine under what condition, the claimed invention preparation/formulation is enabled, since a wide range of steps, processes and ingredients are contemplated and are encompassed as well as a method of **treating all kinds of female subjects** (any female). The results desired appear to be highly dependent on all variables, the relationship of which is not clearly disclosed.

Therefore, without guidance through working example(s), one of ordinary skill in the art would not predict from pages 1-2 of the instant specification to use LH for generating libido and reaching orgasm in "**female subjects"** in the manner claimed in claims 4-6. Thus, the

specification does not enable any person skilled in the art to which it pertains, or which is most nearly connected, to use the invention commensurate in scope with the claims. In the express absence of one or more examples, evidence and sufficient guidance, the skilled artisan would be faced with undue experimentation for practicing the invention.

CLAIMS REJECTION-35 U.S.C. 112 2nd PARAGRAPH

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "said woman" in line 3. There is insufficient antecedent basis for this limitation in the claim.

CLAIMS REJECTION-35 U.S.C. 103(a)

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/64236 A2.

The instantly claimed invention as claimed in claims 4-6 is directed to a method for treating a lack of or low libido and/or a difficulty in reaching orgasm in female subjects, comprising administering parenterally or orally by means of tablets to said woman an effective amount of Luteinizing Hormone (LH).

The prior art of WO 01/64236 ('236 patent) discloses on page 1, under the Background of the Invention, that LH and follicle-stimulating hormone (FSH) are hormones released by the pituitary gland. These hormones regulate the functioning of the gonads and the production and maturation of gametes. LH and FSH are generally released by the pituitary gland upon prior release of a triggering hormone from the hypothalamus. Luteinizing hormone-releasing hormone (LHRH; also known as gonadotropin-releasing hormone or GnRH) is one of the principal hypothalamic hormones that trigger the release of LH and FSH. Thus, release of GnRH represents a control point in the physiological regulation of gonadal function. LH and FSH release is necessary for ovulation in females and for maturation of sperm in males. Accordingly, compounds which inhibit LH and/or FSH release by blocking the action of GnRH, such as GnRH superagonists and antagonists, are useful in the treatment of sex-hormone associated disorders.

Further, on page 2, under Summary of the Invention, the '236 patent continues by stating that the present invention provides GnRH antagonists, and formulations thereof, that are suitable for use *in vivo* and that are able to inhibit both LH and FSH production, wherein the method

includes administering to the subject an GnRH antagonist suitable for the *in vivo* administration and able to reduce both plasma FSH and LH levels in a subject.

Furthermore, on page 6, lines 17-22, the '236 patent states that the invention features a method for modulating, e.g., downregulating or upregulating, libido in a subject, a human. The method includes administering to the subject a GnRH antagonist suitable for *in vivo* administration and able to reduce both plasma FSH and LH levels in a subject, in an amount or in a formulation effective to reduce plasma FSH and LH levels in the subject, e.g., to a symptom alleviating level, thereby modulating libido in the subject. Thus, clearly showing upgrading libido, and as such suggesting to one of ordinary skill in the art to which this invention pertains would be able to reduce LH levels in a female subject including (a human female i.e., woman).

In regard to the term "GnRH antagonist", the '236 patent on page 9, lines 14-18 defines it to include a compound that inhibits the gonadotropin releasing hormone receptor such that release of gonadotropin is inhibited. The term "GnRH antagonist" may be used interchangeably with the term "GnRH-R antagonist" to include compounds that inhibit GnRH-R such that release of both LH and FSH is inhibited.

Further, the term "administering" to a subject is defined to include dispensing, delivering or applying an GnRH antagonist, e.g., GnRH antagonist in a pharmaceutical formulation, to a subject by any suitable route for delivery by either the parenteral or oral route, etc. Also, with respect to the term "effective amount", the '236 patent defines it to include an amount effective, at dosages and for periods of time necessary, to achieve the desired results (See e.g., page 10, lines 13-20).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use or employ the '236 patent's teachings of a method for modulating libido in a subject, comprising administering to a subject a GnRH antagonist suitable for *in vivo* administration and able to reduce both plasma FSH and LH levels in a subject, in an amount or in a formulation effective to reduce plasma FSH and LH levels in the subject to a symptom alleviating level, thereby modulating libido in the subject as claimed in claim 32 of '236 patent. Thus, from the teachings of the prior art, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in treating a lack of or low libido and/or a difficulty in reaching orgasm in the claimed invention because the prior art has clearly shown that suppressing LH would suppress libido and as such, suggests that it is expected to increase libido and/or in reaching orgasm in female subjects including woman in the manner claimed in claims 4-6. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the teachings of the prior art, absent of factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDNCE

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABDEL A. MOHAMED whose telephone number is (571)272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Abdel A Mohamed/
Examiner, Art Unit 1654

/Jon P Weber/
Supervisory Patent Examiner, Art Unit 1657